

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash Aniseed Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Digluconate 0.2% w/v (equivalent to Chlorhexidine Gluconate Solution 1.0% v/v)

For full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Mouth wash.

A clear, colourless liquid with an odour of menthol and aniseed.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Aids prevention of dental plaque formation. Aids the treatment and prevention of gingivitis. For the maintenance of oral hygiene. Promotes gingival healing following periodontal surgery. Management of recurrent oral ulceration. For the treatment of denture stomatitis and oral thrush.

4.2 Posology and method of administration

For oromucosal use.

Adults, the elderly and children: To be used as required up to twice daily. Rinse the mouth thoroughly for about 1 minute with 10ml. The mouthwash should be expelled from the mouth after rinsing.

Prior to dental surgery: Rinse the mouth thoroughly with 10ml for 1 minute. The mouthwash should be expelled from the mouth after rinsing.

Treatment of gingivitis: A course of one month is recommended.

Treatment of denture stomatitis: Soak the denture(s) in solution for 15 minutes twice daily.

Treatment of oral ulceration and oral thrush: Treatment should be continued for 48 hours after clinical resolution.

4.3 Contraindications

Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

For oral use only. Keep away from the eyes and ears. If the solution comes into contact with the eyes, rinse well with water. Keep out of the sight and reach of children. Do not swallow. If symptoms persist, stop using and consult your doctor or dentist.

Chlorhexidine Mouthwash contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Chlorhexidine Mouthwash should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine digluconate is incompatible with anionic agents which are usually present in conventional dentrifices. These should therefore be used before the mouthwash. Rinse the mouth thoroughly with water before using the mouthwash.

4.6 Fertility, pregnancy and lactation

No harmful effects in human pregnancy or during lactation have been reported. Nevertheless like all medicines, care should be exercised and the mouthwash should only be used on the advice of a doctor or dentist.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Skin disorders

Frequency not known: Allergic reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune disorders

Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

Nervous System Disorders

Common: Oral paraesthesia/hypoaesthesia

A superficial discolouration of the dorsum of the tongue may occur which disappears after discontinuation of treatment. Discolouration of the teeth and silicate or composite restorations may also occur. The discolouration is not permanent and may be prevented by brushing daily with conventional toothpaste prior to using the mouthwash and avoiding tannin-containing food and drinks. In some cases a professional prophylaxis (scaling and polishing) may be necessary to completely remove the stain.

Transient disturbances of taste and a burning sensation of the tongue may occur on initial use of the mouthwash but usually diminishes with continued use.

In cases where oral desquamation occurs it may be necessary to discontinue treatment.

Very occasionally, swelling of the parotid glands during use has been reported. If this happens stop using the product and the effect should go away.

In all cases spontaneous resolution has occurred on discontinuation of treatment.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Chlorhexidine is poorly absorbed by the oral route; therefore systemic effects are unlikely even if large volumes are swallowed. However, gastric lavage followed by supportive measures may be used as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A01A B03 – Stomatological preparations, antiinfectives for local oral treatment

Chlorhexidine digluconate is a bisbiguanide antiseptic and disinfectant, which is bactericidal or bacteriostatic against a wide range of gram negative and gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. The antimicrobial activity covers most of the important species occurring in the oral microflora.

5.2 Pharmacokinetic properties

Due to its cationic nature, chlorhexidine digluconate binds strongly to skin, mucosa and other tissues and is thus very poorly absorbed. No detectable blood levels have been found following oral use.

5.3 Preclinical safety data

No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated Polyoxyl Castor Oil

Menthol

Anise Oil

Ethanol (96%)

Aspartame E951

Purified Water

6.2 Incompatibilities

The mouthwash is incompatible with anionic agents which are often present in toothpastes. Therefore these should be used before the mouthwash, rinsing the mouth between applications, or at a different time of day.

6.3 Shelf life

Unopened: 2 years

In-use: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

300ml amber PET bottle with HDPE/PP tamper evident child resistant closure with EPE Saranex liner.

30ml CE marked polypropylene dosing cup

6.6 Special precautions for disposal

No Special Requirements

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited

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Huddersfield

West Yorkshire

HD7 5QH

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0373

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

22/09/2025

10 DATE OF REVISION OF THE TEXT

22/09/2025